Allyn Z. Lite
Michael E. Patunas
Mayra V. Tarantino
LITE DEPALMA GREENBERG & RIVAS, LLC
Two Gateway Center, 12th Floor
Newark, NJ 07102
Tel: 973.623.3000
Fax: 973.623.0858

David M. Hashmall
Jeffrey A. Simes
GOODWIN PROCTER LLP
The New York Times Building
620 Eighth Avenue
New York, New York 10018
Tel.: 212.813.8800
Fax: 212.355.3333

Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TEVA PHARMACEUTICAL INDUSTRIES LTD. and TEVA PHARMACEUTICALS USA, INC.,	:	
Plaintiffs,	:	
v.	:	Civil Action No. _____ Related to C.A. No. 02-3779
SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE,	:	
Defendant.	:	

COMPLAINT AND JURY DEMAND

INTRODUCTION

1. Plaintiffs Teva Pharmaceutical Industries Ltd., and Teva Pharmaceuticals USA, Inc. (collectively, "Teva"), leading manufacturers of generic pharmaceutical products, brings this action against defendant SmithKline Beecham Corporation ("GSK") for breach of contract and breach of the implied covenants of good faith and fair dealing in relation to a settlement

agreement the parties executed in 2005.

2. This lawsuit arises from a previous patent infringement action in this Court between the parties. The prior litigation involved claims by GSK that a generic pharmaceutical product Teva proposed to sell purportedly infringed a patent owned by GSK. After several years of litigation, the parties reached a settlement of the patent dispute. As part of the settlement, the parties entered into a licensing agreement that provided that Teva would be permitted to launch its generic product no earlier than July 21, 2008 and that GSK would not sell a generic equivalent for a limited period of time.

3. Immediately prior to the agreed-upon launch date for Teva's generic product, GSK breached its core obligations to Teva. In disregard of its clear contractual duties, GSK has contacted customers and has sought to persuade them to buy its brand products for use as a generic equivalent – exactly what GSK agreed it would ***not*** do.

4. GSK's actions have already caused substantial injury to Teva. Therefore, Teva brings this complaint to secure the benefit of its bargain with GSK.

PARTIES

5. Plaintiff Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") is a corporation organized and existing under the laws of the State of Israel and having a registered office at 5 Basel Street, P.O. Box 3190, Petach Tikva 49131, Israel. Teva Ltd. is the ultimate parent company of Teva USA.

6. Plaintiff Teva Pharmaceuticals USA, Inc. ("Teva USA" and, collectively with Teva Ltd., "Teva") is incorporated under the laws of the State of Delaware, with its principal place of business in North Wales, Pennsylvania. Teva USA develops, manufactures, and sells generic pharmaceutical products in the United States. Teva USA is an indirect wholly-owned subsidiary of Teva Ltd.

7. Teva Ltd. manufactures the generic lamotrigine tablet product that Teva USA will start selling in the United States in July of 2008. Teva USA holds title to the regulatory approval that authorizes Teva to sell that product.

8. On information and belief, Defendant SmithKline Beecham Corporation is a private corporation organized and existing under the laws of the Commonwealth of Pennsylvania and having a registered office at One Franklin Plaza, Philadelphia, PA 19102. SmithKline Beecham Corporation operates under the business name GlaxoSmithKline ("GSK").

JURISDICTION AND VENUE

9. The Court has subject matter jurisdiction based on Paragraph 10 of the Stipulation and Order of Dismissal entered on April 4, 2005, in Civil Action No. 02-3779, in which Judge Bissell ordered that this Court retained jurisdiction over any matters relating to or arising from the interpretation of the settlement agreement at issue in this dispute.

10. Teva and GSK consented to this Court's exercise of personal jurisdiction for purposes of enforcing the settlement agreement that is the subject of this dispute, as set out in Paragraph 10 of the Stipulation and Order of Dismissal entered on April 4, 2005, in Civil Action No. 02-3779.

11. GSK also consented to this Court's exercise of personal jurisdiction when GSK invoked the jurisdiction of the Court by filing the underlying patent infringement litigation against Teva that gives rise to this dispute in this Court.

12. Venue is proper before this Court, as the Settlement Agreement arises from a patent litigation venued here.

BACKGROUND

The Parties' Products and the Nature of Sales of Generic Equivalent Products

13. GSK sells products containing the active ingredient lamotrigine under the brand

name Lamictal®. These products are approved by the FDA for treatment of patients with epilepsy or bipolar disorder. GSK sells its lamotrigine products in two forms: tablets (25mg, 50mg, 100mg, 150mg, and 200mg) and chewable dispersible tablets (5mg and 25mg). The only form at issue for this dispute is the non-chewable tablet ("tablet"). GSK sells its Lamictal® tablet product pursuant to New Drug Application 20-241, which was approved by the Food and Drug Administration ("FDA") in 1994. For the 12 months ending March of 2008, GSK's sales of Lamictal® tablets in the United States exceeded $2 billion according to IMS data.

14. On or about April 1, 2002, Teva filed Abbreviated New Drug Application ("ANDA") No. 76-388 with the FDA, seeking approval to manufacture and sell generic lamotrigine tablets. The FDA approved Teva's ANDA on August 30, 2006. In approving Teva's ANDA, the FDA found that Teva's lamotrigine tablets are bioequivalent to GSK's Lamictal® tablets – *i.e.*, that Teva's lamotrigine tablets have the same safety and efficacy as GSK's Lamictal® tablets of the same dosage strength.

15. In addition, the FDA categorized Teva's lamotrigine tablets as being "AB-rated" to GSK's Lamictal® tablets. Under the drug selection laws of certain states, such a rating means that pharmacists would be able (or even required) to dispense the lower-cost AB-rated generic instead of the higher-priced branded drug.

The Patent Litigation and Settlement

16. GSK has alleged that it owns U.S. Patent No. 4,602,017 (the "'017 Patent"). On information and belief, the '017 Patent expires on July 22, 2008, and the FDA also has granted GSK an additional six-month period of pediatric exclusivity for the '017 Patent that does not expire until January 22, 2009.

17. GSK filed Civil Action No. 02-3779 and Civil Action No. 02-4537 against Teva in federal court in New Jersey in 2002, alleging that Teva's ANDA infringed the '017 Patent (the

"Patent Litigation").

18. The outcome of the Patent Litigation would have directly affected the date on which Teva would be legally permitted to commence sales of its generic lamotrigine products. If GSK were to prevail, then Teva would have been barred from selling its products until after the expiration of the '017 Patent and any additional exclusivities. That would have prevented Teva from entering the market and selling its products until early 2009 (*i.e.*, until the expiration of regulatory exclusivity). On the other hand, if Teva were to prevail, then Teva would have been permitted to start selling its product immediately upon approval from the FDA, which approval was in fact granted in 2006.

19. Following discovery, the Patent Litigation proceeded to a bench trial before Judge Bissell between January 18 and January 27, 2005. On the final day of trial, Judge Bissell denied GSK's motion for judgment as a matter of law. He instead informed counsel in open court that he planned to find in favor of Teva with respect to one of GSK's patent claims. Judge Bissell did not indicate how he intended to rule on other patent claims at issue. Therefore, the outcome of the patent litigation remained in doubt.

20. Following Judge Bissell's statement, the parties engaged in discussions that resulted in a settlement of the patent litigation. The settlement represents a compromise of reasonably disputed patent claims and defenses. The settlement is set forth in several documents, including a Settlement Agreement dated February 16, 2005, between GSK and Teva USA (the "Settlement Agreement"), and a License & Supply Agreement, also dated February 16, 2005 (the "License Agreement"), between GSK and Teva Ltd. In addition, and pursuant to the Settlement Agreement, the parties submitted a Stipulation and Order of Dismissal in the Patent Litigation which dismissed all claims and counterclaims but also provided that the Court "shall retain jurisdiction over any matters related to or arising from the interpretation or enforcement of the

Settlement Agreement." Judge Bissell signed the Stipulation on April 4, 2005 and it was entered on the Court's docket on April 6, 2005.

21. The License Agreement provides, among other things, that GSK grants to Teva a royalty-free, non-transferable license under the '017 Patent to import, manufacture, have manufactured and have sold Teva's generic lamotrigine products in the United States, starting no earlier than July 21, 2008, at 5:00 p.m. Pacific time, and a waiver of pediatric exclusivity applicable to Teva's generic lamotrigine products.

22. The License Agreement also provides that the license and waiver grants to Teva are ***exclusive***, "including as to [GSK] and its Affiliates and Third Parties with respect to Generic Equivalents." This express exclusivity in the license grant to Teva means that while GSK reserved the right to sell its Lamictal® tablets as branded products, GSK gave up any right for itself and anyone other than Teva to sell Lamictal® tablets or any other products as generic equivalents in any form or fashion for the limited duration of these license provisions.

23. These provisions were an important component of the settlement between the parties and formed part of the inducement to Teva to relinquish the rights and defenses it was asserting against GSK in the Patent Litigation.

GSK's Offers to Sell
its Lamictal® Tablets as Generic Equivalents

24. Facing the imminent entry of Teva's generic lamotrigine products, and the resulting losses on sales of branded Lamictal® tablets as customers elect to purchase Teva's lower-priced generic product, GSK has reneged on the deal it reached with Teva three years ago.

25. On information and belief, GSK has offered customers – including pharmacies, large pharmacy chains, group purchasing organizations, and long-term care facilities – proposals by which customers will commit to purchase GSK's lamotrigine products to be sold as generic

equivalent products to consumers. One such proposal offered by GSK specifically states that participating retail pharmacies are required to "perform system edits ***to dispense GSK Product(s) as the generic*** during the Term of the Agreement." (emphasis added)

26. On information and belief, this GSK proposal calls for the customers to dispense GSK's products using what is known as a "DAW 5" code. This code is used by managed care organizations and state Medicaid programs to signify that a branded product is being dispensed as a generic. For example, the West Virginia Department of Health and Human Services states that use of DAW 5 means "[p]harmacy uses this brand as its generic but realizes it will be paid at the generic rate." Similarly, the Medicaid Provider Services for the State of Colorado recognize that a DAW 5 code signifies "substitution allowed – brand as generic." GSK's proposal to customers that they use the DAW 5 code for transactions further shows GSK's own express recognition that it is selling its branded products for customers to dispense as a generic equivalent.

Injury to Teva

27. On information and belief, the purpose of GSK's improper proposal to customers is to reduce the benefit of Teva's bargain in the Settlement Agreement and the License Agreement by preventing or discouraging customers from substituting Teva's generic product for GSK's Lamictal® brand tablets.

28. Despite the contractual relationship between the parties in the License Agreement, GSK did not provide any advance notice of its actions despite their obvious deleterious effect on the close of business (5 p.m. PDT) July 21, 2008 Teva product launch of which GSK was well aware. Instead, GSK quietly sought to implement its proposal to customers at the last possible minute before Teva's launch, apparently to minimize the possibility that Teva could effectively respond to GSK's ruse. GSK's conduct has had the effect of increasing the expense and effort

Teva has had to undertake in order to successfully launch its generic lamotrigine tablets.

29. GSK's conduct will cause injury to both Teva Ltd. and Teva USA. The injuries to Teva Ltd. and Teva USA are separate, independently compensable components of injury and are not duplicative.

COUNT I
(Breach of Contract)

30. Teva repeats the allegations of the foregoing paragraphs as if incorporated here in full.

31. Teva and GSK entered into valid, binding contracts in the form of the Settlement Agreement and the License Agreement.

32. Teva performed its obligations under the Settlement Agreement and License Agreement.

33. GSK breached a duty imposed by its contract with Teva by, among other things, offering to sell and/or selling its lamotrigine products as generic equivalents.

34. GSK's breach of its contract with Teva caused and will cause Teva to suffer damages.

COUNT II
(Breach of Contract – Good Faith and Fair Dealing)

35. Teva repeats the allegations of the foregoing paragraphs as if incorporated here in full.

36. Teva and GSK entered into valid, binding contracts in the form of the Settlement Agreement and the License Agreement.

37. Teva performed its obligations under the Settlement Agreement and License Agreement.

38. The contracts between Teva and GSK impose duties of good faith and fair dealing on the parties.

39. GSK breached its duties of good faith and fair dealing to Teva by, among other things, offering to sell and/or selling its lamotrigine products as generic equivalents when GSK had agreed in the contract that it would not do so.

40. GSK also breached its duties of good faith and fair dealing by failing to inform Teva of its plans to sell its lamotrigine product as generic equivalents, and by its conduct in launching an effort to injure Teva's launch of the its own lamotrigine product.

41. GSK's breach of its duties of good faith and fair dealing with Teva caused and will cause Teva to suffer damages.

PRAYER FOR RELIEF

WHEREFORE, Teva respectfully requests that the Court:

A. Award Teva its damages suffered as a result of GSK's breaches of its contracts with Teva;

B. Grant Teva preliminary and permanent injunctive relief;

C. Award Teva attorneys' fees and the costs of its efforts to enforce the Settlement Agreement and the License Agreement; and

D. Award Teva any other or additional relief that the Court deems proper.

JURY TRIAL DEMAND

Teva hereby demands trial by jury on all claims to which it is entitled to a jury trial.

Respectfully submitted,

s/Michael E. Patunas
Allyn Z. Lite
Michael E. Patunas
Mayra V. Tarantino
LITE DEPALMA GREENBERG & RIVAS, LLC
Two Gateway Center, 12th Floor
Newark, NJ 07102
Tel: 973.623.3000
Fax: 973.623.0858
alite@ldgrlaw.com
mpatunas@ldgrlaw.com
mtarantino@ldgrlaw.com

David M. Hashmall
Jeffrey A. Simes
GOODWIN PROCTER LLP
The New York Times Building
620 Eighth Avenue
New York, New York 10018
Tel.: 212.813.8800
Fax: 212.355.3333
dhashmall@goodwinprocter.com
jsimes@goodwinprocter.com

Attorneys for Plaintiffs

Dated: July 23, 2008